

WHAT IS CLAIMED:

1. An isolated hepatitis C virus (HCV) asialoglycoprotein selected from the group consisting of E1 and E2.

2. The asialoglycoprotein of claim 1, wherein said asialoglycoprotein is E1.

3. The asialoglycoprotein of claim 1, wherein said asialoglycoprotein is E2.

4. The asialoglycoprotein of claim 2, wherein said E1 asialoglycoprotein is recombinant E1.

5. The asialoglycoprotein of claim 2, wherein said E1 asialoglycoprotein is recombinant E2.

6. A method for producing hepatitis C virus (HCV) asialoglycoproteins suitable for use in a vaccine or immunoassay, which method comprises:

growing a lower eukaryote transformed with a structural gene encoding an HCV asialoglycoprotein selected from the group consisting of E1 and E2 in a suitable culture medium;

causing expression of said structural gene; and

recovering said HCV asialoglycoprotein from said cell culture.

7. The method of claim 6, wherein said lower eukaryote is yeast.

8. The method of claim 7, wherein said yeast is *Saccharomyces*.

9. The method of claim 7, wherein said yeast is phenotypically pmr1.

5 10. The method of claim 6, wherein said HCV asialoglycoprotein structural gene further comprises a polynucleotide encoding a secretion leader functional in said lower eukaryote.

10 11. The method of claim 10, wherein said secretion leader comprises the α -factor secretion leader.

12. A method for producing hepatitis C virus (HCV) asialoglycoproteins suitable for use in a vaccine or immunoassay, which method comprises:

15 growing a mammalian host cell transformed with a structural gene encoding an HCV asialoglycoprotein selected from the group consisting of E1 and E2 in a suitable culture medium;

20 causing expression of said structural gene under conditions inhibiting sialylation; and

recovering said HCV asialoglycoprotein from said cell culture.

25 13. The method of claim 12, wherein said condition inhibiting sialylation comprises expression of E1 or E2 at a rate sufficient to inhibit transport of glycoproteins from the endoplasmic reticulum to the golgi.

14. The method of claim 12, wherein said conditions inhibiting sialylation comprise:

presence of a sufficient amount of a calcium modulator to cause release of proteins within the host cell's endoplasmic reticulum.

5 15. The method of claim 14, wherein said calcium modulator is thapsigargin.

16. A method for purifying hepatitis C virus (HCV) asialoglycoproteins, which method comprises:

10 contacting a composition containing HCV asialoglycoproteins with a mannose-binding protein; and
isolating the portion of the composition which binds to said mannose-binding protein.

13 17. The method of claim 16, wherein said mannose-binding protein is a lectin selected from the group consisting of ConA and GNA.

18. The method of claim 16, wherein said mannose-binding protein is immobilized on a support.

20 19. The method of claim 18, wherein:
said contacting comprises incubation of said composition containing HCV asialoglycoproteins in a column comprising a mannose-binding lectin immobilized on a support, for a period of at least one hour; and
said isolating comprises eluting said HCV asialoglycoproteins with
25 mannose.

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20. An assay kit for detecting the presence of hepatitis C virus (HCV) asialoglycoproteins, said kit comprising:

Sub. B1
a solid support;
a mannose-binding protein; and
an antibody specific for said HCV asialoglycoprotein;
wherein one of said antibody and said mannose-binding protein is bound to
5 said solid support.

21. The assay kit of claim 20, wherein said mannose-binding protein is
GNA.

10 22. The assay kit of claim 20, wherein said antibody is bound to said
support and said mannose-binding protein is bound to a detectable label.

23. The assay kit of claim 20, wherein said mannose-binding protein is
bound to said support and said antibody is bound to a detectable label.

24. In a method for determining exposure to or infection by hepatitis C
virus (HCV), the method wherein any HCV within a sample of body fluid is concentrated
by contact with a mannose-binding protein prior to assay.

20 25. The method of claim 24, wherein said mannose-binding protein is
GNA.

26. A cell transformed with a vector for recombinant expression of a
hepatitis C virus (HCV) asialoglycoprotein, wherein said vector comprises a structural
25 gene encoding a glycosylation signal, an HCV asialoglycoprotein, a regulatory sequence
operable in said host cell and capable of regulating expression of said HCV asialoglyco-
protein, and a selectable marker; wherein said cell does not sialylate glycoproteins.

27. The cell of claim 26, wherein said cell is a glycosylation-defective yeast strain.

28. The cell of claim 26, wherein said vector comprises a vaccinia virus vector.

29. A method for reducing or eliminating the presence of hepatitis C virus (HCV) in plasma, serum, or other biological liquids which method comprises:
contacting said biological liquid with a mannose-binding protein specific for mannose-terminated glycoproteins; and
separating said biological liquid from said mannose-binding protein.

30. The method of claim 29 wherein said mannose-binding protein is GNA.

31. A method of inducing an immune response in an animal, which method comprises:
providing a vaccine composition comprising an effective amount of a hepatitis C virus (HCV) asialoglycoprotein in a pharmaceutically acceptable vehicle;
administering said vaccine composition to said animal.

32. The method of claim 31, wherein said HCV asialoglycoprotein is E1.

33. The method of claim 31, wherein said HCV asialoglycoprotein is E2.

34. The method of claim 31, wherein said HCV asialoglycoprotein is a purified E1/E2 aggregate.

35. The method of claim 31, wherein said animal is a primate.

36. A hepatitis C virus (HCV) asialoglycoprotein composition, comprising:
purified HCV E1/E2 asialoglycoprotein aggregate.

37. The composition of claim 36, wherein said HCV E1/E2 asialoglycoprotein aggregate is at least 40% pure.

38. The composition of claim 37, wherein said HCV E1/E2 asialoglycoprotein aggregate is at least 50% pure.

39. The composition of claim 38, wherein said HCV E1/E2 asialoglycoprotein aggregate is at least 60% pure.

40. The composition of claim 36, wherein said HCV E1/E2 asialoglycoprotein aggregate is substantially free of other HCV proteins.

41. The composition of claim 36, wherein said aggregate has a molecular weight of about 107 kD.

42. The composition of claim 36, wherein said aggregate has a molecular weight of about 800 kD.

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